K131647

3. 510(K) SUMMARY

1. Applicant/Sponsor:

Corin USA
5670 West Cypress Street
Suite C
Tampa, Florida 33607
Establishment Registration No.: 1056629

2. Contact Persons:

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SEP 27 2013

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3. Proprietary Name: Corin Trinity Acetabular System with Extra short Heads and 28mm Extra long Head

4. Common Name: Hip Prosthesis

5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)
Product Codes: LZO, MEH

6. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Corin Trinity Acetabular System (K093472)
- Corin Trinity Acetabular System with HXLPE Liners (K110087)
- Corin Trinity Acetabular System with Extra Long Heads (K130343)
- Biomet M^{2}a™ Magnum™ System (K993438, K003363, K042037)

7. Device Description:

The Trinity Acetabular System is a modular acetabular cup system consisting of a press fit,

titanium alloy shell; acetabular liners in neutral offset, +4mm offset, +4mm oblique, neutral 4mm EPW; and BIOLOX *delta*™ ceramic and CoCrMo modular heads. The ceramic and CoCrMo modular heads are compatible with Corin titanium femoral stems.

The purpose of this submission is to add 28mm (-5mm offset), 32mm (-6mm offset), 36mm (-8mm offset), and 40mm (-8mm offset) CoCrMo extra short femoral heads to the Trinity Acetabular System, and complete the line of extra long heads with the addition of a 28mm (+7mm offset) CoCrMo heads.

The Trinity Acetabular System is intended for use in total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

8. Intended Use / Indications:

The indications for the Trinity Acetabular System as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Trinity Acetabular System is intended for cementless, single use only.

9. Summary of Technologies/Substantial Equivalence:

The additional components of the Trinity Acetabular System are identical to the predicate devices (K093472, K1100087, K130343) in terms of intended use and indications, and materials, and similar in sizes, designs and performance. The additional components of the Trinity Acetabular System are identical to the predicate devices (K993438, K003363, K042037) in terms of materials, and similar in sizes, designs, performance, and intended use and indications. Based on these characteristics, the additional components of the Trinity Acetabular System are believed to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Non-clinical testing conducted to demonstrate substantial equivalence includes: impingement testing, range of motion testing, and stem fatigue testing and stem neck fatigue testing with head offsets representing the worse-case scenario for the compatible stems.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the additional components of the Trinity Acetabular System and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Corin USA
Ms. Diana L. Martone
Regulatory Affairs Associate
5670 West Cypress Street
Suite C
Tampa, Florida 33607

Re: K131647
Trade/Device Name: Trinity Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: August 20, 2013
Received: August 21, 2013

Dear Ms. Martone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K131647

Device Name: Trinity Acetabular System

Indications for Use:

The indications for the Trinity Acetabular System as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
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The Trinity Acetabular System is intended for cementless, single use only.

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices